

DEPARTMENT OF HEALTH AND HUMAN SERVICES

J. Scott Thenell
Regulatory Affairs
Seminis Vegetable Seeds, Inc.
Research
37437 State Highway 16
Woodland, CA 95695

2/10/97

Dear Mr. Thenell:

This is in regard to your genetically modified squash about which you initiated consultations with the Agency on February 26, 1997. The new squash variety has been modified for resistance to cucumber mosaic virus, zucchini yellow mosaic virus and watermelon mosaic virus 2 by insertion of the coat protein genes from the three viruses.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new squash variety on February 26, 1997 and supplementary information on May 6, 1997. These communications informed FDA of the steps taken by Seminis Vegetable Seeds to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Seminis Vegetable Seeds has concluded that the new squash variety is not materially different in composition, safety, or other relevant parameters from squash currently on the market, and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF0043 and that will be maintained in the Office of Premarket Approval.

Based on the information Seminis Vegetable Seeds has presented to FDA, we have no further questions concerning virus-resistant squash line CZW3 at this time. However, as you are aware, it is Seminis Vegetable Seeds's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,
/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-13, HFS-200, HFS-205, HFS-206, HFS-225, HFS-226, HFS-246, HFS-247, HFV-200,
HFV-221, HFV-199, HFV-228, BNF43